510(k) Summary of Safety & Effectiveness

Prepared in accordance with 21 CFR Part 807.92(c)

The assigned 510(k) number is: K 101091

Applicant Information:

JUN 2 5 2010

Date Prepared:

June 14, 2010

Name:

ZONARE Medical Systems, Inc.

420 North Bernardo Avenue Mountain View, CA 94043

Contact Persons:

Linda J. Moore

Director, Regulatory Affairs & Quality Assurance

Telephone Numbers: 650-230-2724

Fax Number:

650-967-9036

Email

lmoore@zonare.com

Device Information:

Trade Name:

ZONARE z.one *Ultra* Ultrasound System

Device Name:

ZONARE Diagnostic Ultrasound System

	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

Marketed Device(s): The ZONARE z.one Ultra Ultrasound System (K022858), (K082326), EPMed Systems

(St. Jude, K031066) (K073709), Philips HD11 (K062247), and Sonosite, Inc. (K053069)

devices currently in commercial distribution.

<u>Device Description:</u> The z.one Ultra is a general purpose diagnostic ultrasound system which consists of a combination of portable scanner(s) less than 10 inches wide and 3 inches high, embedded in the cart, or that can be held by the user in one hand. They include buttons for controlling the system and may have a screen that display ultrasound mages and user interface or be without the screen (monitor) and user interface. The portable scanner can be held by the user in one hand and accommodates a removable transducer module. Signals received from the transducer module are digitized and preprocessed. The transducer module comes into contact with the patient and both transmit and receive ultrasound energy.

The docking station (aka carts) provides holders for the portable scanner, and transducer modules, as well as battery chargers and other accessories. The modification for this submission includes new indication for use and off the shelf transducers.

Indications for Use: The device is intended for use by a qualified physician for ultrasound evaluation of Ophthalmic; Fetal/obstetric, gynecological; Abdominal (renal, GYN/Pelvic; Intra-operative (abdominal, thoracic, and vascular), Intra-operative neurological; Pediatric; Small organ (thyroid, breast, testes, etc), Adult & Neonatal Cephalic; Trans-rectal, Trans-vaginal, Trans-cranial, Trans-esophageal (non-cardiac and cardiac); Musculoskeletal (conventional & superficial); 3D/4D; Cardiac – Adult/Pediatric/Fetal; Intra-Cardiac; Pelvic; Peripheral vascular; harmonic tissue and contrast imaging and Tissue elasticity.

<u>Comparison with Predicate Device:</u> With respect to features and applications, the ZONARE z.one Ultra with the new ophthalmic indication for use and the off the shelf intra-cardiac echo catheter (View-Flex) is comparable and substantially equivalent to the currently marketed ZONARE z.one and the predicate devices listed in predicate devices section in terms of portability, features and functionality. Additionally, they have the same important safety and effectiveness features, as well as design, materials, and construction.

<u>Non-clinical tests:</u> The device has been evaluated according to the applicable medical device quality systems, safety standards for acoustic output, biocompatibility, verification and validation, cleaning, and disinfection effectiveness as well as for thermal, electrical, and mechanical safety, those applicable to ZONARE's ultrasound product are:

ISO 14971	Medical Devices – applications of risk management to medical devices
IEC/UL 60601-1	Medical Electrical Equipment (MEE) - General Requirements for Safety
IEC 60601-1-1	Medical Electrical Equipment for Systems
IEC 60601-1-2	EMC
IEC 60601-1-4	MEE – Programmable electrical medical systems
IEC 60601-2-37	Safety of ultrasonic medical diagnostic and monitoring equipment
IEC 62304	Medical Device software – software life cycle processes
ISO 10993	Biological evaluation of medical devices
AlUM	Medical Ultrasound Safety, American Institute of Ultrasound in Medicine (2002)

Clinical Tests: Non Required

<u>Conclusion</u>: The device conforms to applicable medical device safety standards and compliance for safety and effectiveness is verified through defined evaluation and market surveillance. The ZONARE z.one Ultra Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices current cleared for market.



Food and Drug Administration 10903 New Hampshire Avenue Document Control Room –WO66-G609 Silver Spring, MD 20993-0002

JUN 2 5 2010

ZONARE Medical Systems, Inc. % Mr. Mark Job Responsible Third Party Official Regulatory Technology Services LLC 1394 25th Street NW BUFFALO MN 55313

Re: K101091

Trade/Device Name: The z.one Ultra Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: June 9, 2010 Received: June 10, 2010

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with The z.one Ultra Ultrasound System, as described in your premarket notification:

Transducer Model Number

Curvilinear Transducer C4-1

Curvilinear Transducer C5-2

Curvilinear Transducer C6-2

Curvilinear Transducer C9-3

Curvilinear Transducer C8-3 (3D/4D)

Curvilinear Transducer C9-4t

Phase (Sector) Array Transducer P4-1

Phase (Sector) Array Transducer P4-1c

Phased (Sector) Array Transducer P10-4

Endo-Cavity Transducer E9-4

Endo-Cavity Transducer E9-4 (3D)

Linear Transducer L10-5

Linear Transducer L8-3
Linear Transducer L12-4v
Linear Transducer L14-5sp
Linear Transducer L14-5w
Tran-Esophageal Transducer P8-3T

St. Jude EP ViewFlex PLUS ICE Catheter model # VF-PM Part #09-2005

A2CW (Common name Pencil Probe) A5CW (Common name Pencil Probe)

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,

Acting Director

Division of Radiological Devices

Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and Radiological Health

Enclosure(s)



Indications for Use Statement

510(K) Number (if known):K101091	
Device Name: The z.one Ultra Ultrasound system	· ·
Indications for Use: The device is intended for use by a question of Ophthalmic; Fetal/obstetric, gynecological; Abdominal (re (abdominal, thoracic, and vascular), Intra-operative neuroletestes, etc), Adult & Neonatal Cephalic; Trans-rectal, Trans (non-cardiac and cardiac); Musculoskeletal (conventional adult/Pediatric/Fetal; Intra-Cardiac; Pelvic; Peripheral vas and Tissue elasticity.	nal, GYN/Pelvic; Intra-operative ogical; Pediatric; Small organ (thyroid, breast, s-vaginal, Trans-cranial, Trans-esophageal & superficial); 3D/4D; Cardiac —
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·	
Prescription Use AND/OR (Part 21 CFR 801 Subpart D)	Over-The-Counter Use(21 CFR 801 Subpart C)
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Page 1 of _

Diagnostic Ultrasound Indications for use 1.3

510(K) Numbe	er (if known):	

System Name: ZONARE z.one Ultra Ultrasound Diagnostic System

Device Name: Union of all Transducer Types

Indications for Use: This device is intended for use by a qualified physician for ultrasound evaluation of the following: Fetal, Abdominal, Intraoperative, Pediatric, Ophthalmic, Intra-cardiac, Small organ/parts (breast/testes, thyroid, etc), Transvaginal, Transrectal, Transcranial, Trans- esoph, Trans-urethral, OB/GYN, Cardiac, Pelvic, Neonatal/Adult cephalic. Vascular, 3D/4D, Tissue elasticity, Musculoskeletal, cardiac, Superficial Musculoskeletal, and Peripheral Vascular applications and others as shown below.

Clinical Applicat	ion	Mode	of Oper	ation 💥	CWD	Total Control of the		
General	Specific	В	М	PWD ²	CWD CWD Aux	Color Doppler ³	Combined Modes ⁴	Other ^{5, 8}
Ophthalmic	Ophthalmic	N		N		N	N	
	Fetal	P	P	P	P	P	P	P ⁵
	Abdominal	P	P	P	P	P	P	P ⁵
	Intra-operative (Specify) ⁶	P	P	P		P	P	P ^ś
	Intra-operative (Neuro)	P		P	<u> </u>	P	P	P ⁵
	Laparoscopic				<u></u>			
	Pediatric	P	P	P	P	P	P	P ⁵
	Pediatric Aux	ļ			P			
	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	P		P	P	P ⁵
	Neonatal Cephalic	P	P	P	P	P	P	P ⁵
General	Adult Cephalic	P	P	P	P	P	P	P ⁵
Application	Trans-rectal	P	P	P		P	P	P ⁵
	Trans-vaginal	P	P	P		P	P	P ⁵
	Trans-urethral				<u> </u>	1		<u> </u>
	Trans-esoph. (non- Card.)	P	P	P	P	Ρ.	P	P ⁵
	Musculo-skel. (Conventional)	P	P	P		P	P	P ^{5, \$}
,	Musculo-skel. (Superficial)	P	P	P		P	P	P ^{5, 8}
	Intra-luminal		1					
	Other (Specify) (3D/4D)	P	P	P		P	P	
	Cardiac Adult	\mathbf{P}^{I}	P	P	P	P	P	P ⁵
	Cardia Adult Aux				P			
	Cardiac Pediatric	P	P	P	P	P	P	P ⁵
Cardiac	Cardiac Pediatric Aux	1	ļ		P		1	↓
	Trans-esoph. (Cardiac)	· P	P	P	P	P	P	P ⁵
	Other (Specify) (3D/4D)	P	P	P	P	P	Р.	
	Other (Intra-Cardiac)*	P	P	P		P		
	Peripheral Vessel	P	P	P	P	P ·	P	P ³
Peripheral vascular	Peripheral Vessel Aux				P			
	Other (Specify) (3D/4D)	p .	P	P		P	P	

N = new indication; P = previously cleared by FDA 510(k) K022858 & K082326, *ST. Jude # 073709 E=Added under Appendix E

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Office of In Vitro Diagnostic Devices		
Evaluation and Safety		
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SIGN Color and ZONADE Malical Contains In-		

Includes B-Mode and Harmonic (contrast) imaging (HI)

² Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

³ Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

⁴ Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)
⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

510(K) Number (if known):_		
System Name: ZONARE z.on	e Ultra Ultrasound	Diagnostic System

Device Name: Curvilinear Transducer C4-1

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	manalia in in	Móde	of Opera	ion 🎉 🙏	see suite de	. AL		de Baldi si
General (Track I Only)	Specific (Track I & III)	В	М	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other ⁵ ,
Ophthalmic	Ophthalmic					,		
	Fetal	E	E	E		E	E	
	Abdominal	E	E	E		E	Е	
	Intra-operative (Specify) ⁷		+ 2					
	Intra-operative (Neuro)						-	
•	Laparoscopic							
	Pediatric	Е	E	E		E	Ε .	
	Small Organ (Thyroid, Breast,							
	Testes, etc.)		<u> </u>			ļ		٠ .
	Neonatal Cephalic		 	<u> </u>			<u> </u>	
`	Adult Cephalic		ļ			· .		
	Trans-rectal							
	Trans-vaginal						ļ	
	Trans-urethral		<u> </u>					
	Trans-esoph. (non- Card.)		ļ. <u>.</u>					,
	Musculo-skel. (Conventional)	Е	E	Е .		E		
	Musculo-skel. (Superficial)						•	,
	Intra-luminal		<u> </u>			<u> </u>		
	Other (Specify) (3D/4D) contrast	E	Е	Е		E	E	
	Cardiac Adult	\mathbf{E}^{1}	Е	Е		E	E	
	Cardiac Pediatric		1					
Cardiac	Trans-esoph.							
	(Cardiac)							
	Other (Specify)		1	1			<u> </u>	
Peripheral	Peripheral vascular					1		
vascular	Other (Specify)	<u> </u>	1	1				<u> </u>

N = new indication; P=previously cleared by FDA 510(k), E=Added under Appendix E

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510(K) K101091

¹ Includes B-Mode and Harmonic (contrast) imaging (HI)

² Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

³ Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Freehand tissue elasticity

510(K)	Numbe	er (if k <mark>now</mark> i	ı):			
System	Name: 2	ZONARE z	one Ultra	Ultrasound	Diagnostic	System

Device Name: Curvilinear Transducer C5-2

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Glinical Applicat	iốn 🚜 🚧 💥	Mode	of Opera	ition.		WX C		tida:
General	Specific (Track I & III)	В	М	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other ^{5,}
Ophthalmic	Ophthalmic							
	Fetal	P	P	P		P	P	P ⁵
	Abdominal ⁶	P	.P	P		P	P	P ⁵
	Intra-operative (Specify)							
	Intra-operative (Neuro)					<u>.</u>		
	Laparoscopic	<u> </u>	ļ <u></u>			<u> </u>		<u> </u>
	Pediatric	P	P	P		P	P	P ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic	 	 	 	 	 	<u> </u>	<u> </u>
General	Adult Cephalic	╂━╌	+	 		 	<u> </u>	
applications	Trans-rectal	1	 			-		-
	Trans-vaginal	 	+	+	 	 		
	Trans-urethral	 	1	 				
	Trans-esoph. (non-			-				
	Musculo-skel. (Conventional)						· <u></u>	
	Musculo-skel. (Superficial)							
	Intra-luminal	<u> </u>			ļ <u>.</u>			
	Other (Specify) (3D/4D)					<u> </u>		
	Cardiac Adult	1						
	Cardiac Pediatric					<u> </u>		
Cardiac	Trans-esoph.	1	1					
	(Cardiac)	<u> </u>		_		<u> </u>	ļ	\
	Other (Specify)	1		 	ļ <u>.</u>		<u> </u>	1_5
Peripheral	Peripheral Vascular	P	P	P	<u> </u>	P	P	P ⁵
Vascular	Other (Specify)				<u> </u>	F-411-1	<u> </u>	<u> </u>

N = new indication; P=previously cleared by FDA 510(k) K022858 & K082326, E=Added under Appendix E

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510(K) <u>K/O 1091</u>

¹ Includes B-Mode and Harmonic (contrast) imaging (HI)

² Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)
³ Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

⁴ Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

⁵ Color M-Mode (CM)
6 Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Freehand tissue elasticity

510(K) Number (if known):	
System Name: ZONARE z.one Ultra	Ultrasound Diagnostic System

Device Name: Curvilinear Transducer C6-2

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Applicat	ion .	-Mode	of Opera	tion 📖 🔻	, arie			
General	Specific (Track I & III)	В	М	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other ^{5,}
Ophthalmic	Ophthalmic							
	Fetal	P	P.	P		P	P	P ⁵
	Abdominal ⁶	P	P	P		P	P	P ⁵
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic					<u> </u>		
	Pediatric	P	P	P		P	P	P ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)		<u> </u>					
General	Neonatal Cephalic				, ,			
applications	Adult Cephalic							
applications	Trans-rectal					,		[-
	Trans-vaginal	i <u></u>						
	Trans-urethral			l		ļ		
	Trans-esoph. (non- Card.)							
	Musculo-skel. (Conventional)		•		:			
,	Musculo-skel. (Superficial)							
	Intra-luminal		ļ					<u> </u>
	Other (Specify) (3D/4D)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric		}					
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral	Peripheral Vascular	P	P	P		P	P	P ⁵
Vascular	Other (Specify)							

N = new indication; P=previously cleared by FDA 510(k) K022858 & K082326, E=Added under Appendix E

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Office of In Vitro Diagnostic Devices Evaluation and Safety

510(K) /101091

¹ Includes B-Mode and Harmonic (contrast) imaging (HI)

² Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)
Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Freehand tissue elasticity

510(K) Number (if known):			
System Name: ZONARE z.one	Ultra Ultrasound	Diagnostic	System

Device Name: Curvilinear Transducer C9-3

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	on a second	Möde	of Opera	tion 🔣	· Carre		a esperant	
General	Specific (Track I & III)	В	М	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other ⁵ ,
Ophthalmic	Ophthalmic			·			,	
	Fetal	P	P	P		P	P	P ⁵
	Abdominal ⁶	P	P	P		P	P	P ⁵ .
	Intra-operative (Abdominal)	P	P	P	P	P	P	P ⁵
	Intra-operative (Vascular)	P	P	P	P	P	P	P ⁵
	Laparoscopic	ļ	<u> </u>		· ·	<u> </u>	<u> </u>	
	Pediatric	P	P ·	P		P	P	P ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)							
C1	Neonatal Cephalic				1			
General applications	Adult Cephalic		1			1		
applications	Trans-rectal							
	Trans-vaginal							
,	Trans-urethral					l		Ī
	Trans-esoph. (non- Card.)							
	Musculo-skel. (Conventional)	P	P	P	P	P	P	P ⁵
	Musculo-skel. (Superficial)	P	P	P	P	P	P	P ⁵
	Intra-luminal	1	J	<u> </u>	<u> </u>		ļ	
	Other (Specify) (3D/4D)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)				,			
	Other (Specify)	1						
Peripheral	Peripheral Vascular	P	P	P	1	P	P	P ⁵
Vascular	Other (Specify)		1					

N = new indication; P=previously cleared by FDA 510(k) K082326, E=Added under Appendix E

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¹ Includes B-Mode and Harmonic (contrast) imaging (HI)

² Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

³ Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

⁴ Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Freehand tissue elasticity

510(K) Number (if known):	
System Name: ZONARE z.one Ultra	Ultrasound Diagnostic System

Device Name: Curvilinear Transducer C8-3 (3D/4D)

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Glinical Applicati	on it	Mode	of Opera	tion 🛊 🙀	L. A.	Tak a sin		
General	Specific (Track I & III)	В	М	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other ^{5,}
Ophthalmic	Ophthalmic							
. •	Fetal	P	P	P		P	P	P ⁵
	Abdominal ⁶	P	P	P		P	P	P ⁵
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic	<u> </u>			<u> </u>	<u> </u>		
	Pediatric	P.	P	P		P	P	P ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)							
C1	Peonatal Cephalic							
General applications	Adult Cephalic		Ţ			•		•
applications	Trans-rectal					·		
	Trans-vaginal	I						
	Trans-urethral					-		
	Trans-esoph. (non- Card.)							
	Musculo-skel. (Conventional)		ļ					
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify) (3D/4D)	P	P	P		P	P	P ⁵
	Cardiac Adult		i					
	Cardiac Pediatric			<u> </u>				
Cardiac	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral	Peripheral Vascular	P	P	P		P	P	P ⁵
Vascular	Other (Specify)			1				

N = new indication; P=previously cleared by FDA 510(k) K082326, E=Added under Appendix E

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Evaluation and Safety	

¹ Includes B-Mode and Harmonic (contrast) imaging (HI)

² Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

³ Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Freehand tissue elasticity

System Name: ZONARE z.one Ultra Ultrasound Diagnostic System

Device Name: Curvilinear Transducer C9-4t

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	non a constant de la	Mode	of Opera	tion 🔊 🗀		Silvania di A	eraneza.	18 M
General (Track I Only)	Specific (Track I & III)	В	М	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other ^{5,}
Ophthalmic	Ophthalmic							
	Fetal Abdominal Intra-operative (Specify) ⁷ Intra-operative (Neuro) Laparoscopic Pediatric Small Organ	E	E	E		E	E E	
	(Thyroid, Breast, Testes, etc.) Neonatal Cephalic	E	Œ	Е		E	E	
General	Adult Cephalic			1				
application	Trans-rectal	ļ. <u> </u>	ļ		ļ	ļ		
	Trans-vaginal	!	ļ <u>-</u>	ļ		<u> </u>		
	Trans-urethral Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	E	Е	E		Е	Е	
	Musculo-skel. (Superficial)	Е	Е	E		Е	E	
	Intra-luminal			ļ			ļ	
	Other (Specify) (3D/4D) Vet abdominal	E	E	E		E	E ·	
	Cardiac Adult							
,	Cardiac Pediatric	E	E	E	<u> </u>	E	Е	ļ. <u></u>
Cardiac	Trans-esoph. (Cardiac)							
	Other (Specify) vet cardiac	Е	Е	E		E	E	
Peripheral	Peripheral vascular	<u> </u>	1	ļ	<u> </u>	1		
vascular	Other (Specify)	<u> </u>		<u> </u>	<u> </u>	<u> </u>	<u>1</u>	<u> </u>

N = new indication; P=previously cleared by FDA

E=Added under Appendix E

¹ Includes B-Mode and Harmonic (contrast) imaging (HI)

³ Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

⁵ Color M-Mode (CM)

⁸ Freehand tissue elasticity

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Evaluation and Safety
510(K) K101091

² Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

⁴ Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

510(K) Number (if known):				
System Name: ZONARE z.one	Ultra	Ultrasound	Diagnostic	System

Device Name: Phase (Sector) Array Transducer P4-1

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

General	Specific			i"		Color	Combined	T Other
	(Track I & III)	В	M	PWD ²	CWD	Doppler ³	Modes ⁴	8
Ophthalmic	Ophthalmic			ļ		·		<u> </u>
	Fetal	P	P	P	P	. P	P	P ⁵
	Abdominal ⁶	P	P	P	P	P	P	P ⁵
	Intra-operative (Specify) ⁷				i			<u> </u>
	Intra-operative (Neuro)		,					
	Laparoscopic							<u> </u>
	Pediatric	P	P	P	P	P	P	P ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)							
a 1	Neonatal Cephalic	P	P	P	P	P	P	P ⁵
General	Adult Cephalic/ trans cranial	P	P	P	P	P	P	P ⁵
	Trans-rectal	•						
	Trans-vaginal							
	Trans-urethral	Ţ						
	Trans-esoph. (non- Card.)					•		
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	P	P	P	P	P	P	P ₂
	Cardiac Pediatric	·P	P	P	P	Р.	P	P ⁵
	Trans-esoph. (Cardiac)							
	Other (Specify) (3D/4D)							
Peripheral	Peripheral Vascular	P	P	P	P	P	P	P ⁵
vascular	Other (Specify)	1			1			7

N = new indication; P=previously cleared by the FDA 510(k) K082326, E=Added under Appendix E

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510(K) K10 1091

¹ Includes B-Mode and Harmonic (contrast) imaging (HI)
2 Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

³ Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

⁴ Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Freehand tissue elasticity

510(K) Number (if known)):
System Name: ZONARE z.	one Ultra Ultrasound Diagnostic Syster

Device Name: Phase (Sector) Array Transducer P4-1c

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	ion a series and a	Mode	of Opera	tion				
General	Specific (Track I & III)	В	М	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other ³
Ophthalmic	Ophthalmic				,			
Орншание	Fetal	P	P	P	P	P	P	P ⁵
	Abdominal ⁶	P	P	P .	P	P	P	P ⁵
	Intra-operative (Specify) ⁷							
	Intra-operative					ł		
	(Neuro)			'		<u> </u>		
	Laparoscopic		<u> </u>		<u> </u>		<u> </u>	1
	Pediatric	P	P	P	P	P	P	P ⁵
•	Small Organ (Thyroid, Breast, Testes, etc.)							,
	Neonatal Cephalic	P	P	P	P	P	P	P ⁵
General	Adult Cephalic/ trans	P	Р	P	P	Р	Р	P ⁵
application	cranial	P	P	r	P	P	P	P
	Trans-rectal			l <u>.</u> .	<u> </u>			
	Trans-vaginal		J	1	<u>]</u>			
	Trans-urethral	İ	l	!				
	Trans-esoph. (non- Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel.	l				-		
	(Superficial)			<u> </u>	<u></u>			
	Intra-luminal					<u> </u>		
	Other (Specify)				<u> </u>	1		
	Cardiac Adult	$\mathbf{P}^{\mathbf{I}}$	P	P	P	P	P	P ⁵
	Cardiac Pediatric	P	P	P	P	P	P	P ⁵
Cardiac	Trans-esoph. (Cardiac)							
	Other (Specify) (3D/4D)contrast	E	E	E .		Е	E	E ⁵
Peripheral	Peripheral Vascular	P	P	P	P	P	P	P ⁵
vascular	Other (Specify)	Ţ						

N = new indication; P=previously cleared by the FDA 510(k) K082326, E=Added under Appendix E

1 Includes B-Mode and Harmonic (contrast) imaging (HI)

2 Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

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510(K) K10109	<u>/</u>	

Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Freehand tissue elasticity

510(K) Nun	nber (if known):			
System Nam	e: ZONARE z.	one Ultra	Ultrasound	Diagnostic S	vsten

Device Name: Phased (Sector) Array Transducer P10-4

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	on the second	Mode	of Opera	tion 3	r (preside	A STATE OF THE STATE OF	PARTY FOR THE	
General	Specific (Track I & III)	В	M	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other5,
Ophthalmic	Ophthalmic		<u> </u>					
	Fetal	P	P	P	P	P	P	P ⁵
	Abdominal ⁶	P	P	P	P	P	P	P ⁵
•	Intra-operative (Specify) ⁷	Р	P	P	·	P	P	P ⁵
,	Intra-operative (Peuro)	P	P	P		P	P	P ⁵
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	· P ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)							
General	Neonatal Cephalic	P	P	P	P	P	P	P ⁵
application	Adult Cephalic/ trans	P	Р	Р	Р	Р	P	P ⁵
appuçation	cranial	P	l r	r	P	P	P	_ P
	Trans-rectal							
	Trans-vaginal		· ·					
	Trans-urethral	·						
	Trans-esoph. (non- Card.)						. ,	
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)	-						
	Intra-luminal						_	
	Other (Specify)							
	Cardiac Adult	P	P	P	P	P	P	P ⁵
	Cardiac Pediatric	P	P	P	P	P	P	P ⁵
Cardiac	Trans-esoph. (Cardiac)				,			
	Other (Specify) (3D/4D)							
Peripheral	Peripheral Vascular	P	P	P	P	P	P	P ⁵
vascular	Other (Specify)					1		1

N = new indication; P=previously cleared by the FDA 510(k) K082326, E=Added under Appendix E

510(K) 510 109

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¹ Includes B-Mode and Harmonic (contrast) imaging (HI)

Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)
Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

⁴ Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Freehand tissue elasticity

System Name: ZONARE z.one Ultra Ultrasound Diagnostic System

Device Name: Endo-Cavity Transducer E9-4

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	on was a second of	Mode	of Opera	tion ,	an bh			MATERIA.
General (Track I Only)	Specific (Track I & III)	В	M	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other ⁵
Ophthalmic	Ophthalmic					ļ		<u></u>
	Fetal Abdominal Intra-operative	P	P	P		P	P	P ⁵
	(Specify) ⁷ Intra-operative (Neuro)				-			
	Laparoscopic . Pediatric					· · · · · · · · · · · · · · · · · · ·		
	Small Organ (Thyroid, Breast, Testes, etc.)					,		
	Neonatal Cephalic							
General	Adult Cephalic	P	P	P		P	P	P ⁵
application	Trans-rectal	P		P		P	P	P ⁵
-	Trans-vaginal Trans-urethral	P	P	P	ļ	P	P	P
	Trans-esoph. (non- Card.)							
	Musculo-skel. (Conventional)				 			
	Musculo-skel. (Superficial)							
	Intra-luminal		 			 		
	Other (Specify) (3D/4D)			-				
	Cardiac Adult	1.	1		İ	İ		1
	Cardiac Pediatric	1					<u> </u>	
Cardiac	Trans-esoph. (Cardiac)							
	Other (Specify)		1	1				
Peripheral	Peripheral vascular	1					1	
vascular	Other (Specify)				1			

N = new indication; P=previously cleared by FDA 510(k) K022858 & K082326, E=Added under Appendix E

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¹ Includes B-Mode and Harmonic (contrast) imaging (HI)

² Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)
Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Freehand tissue elasticity

510(K) Numbe	er (if known):		

System Name: ZONARE z.one Ultra Ultrasound Diagnostic System

Device Name: Endo-Cavity Transducer E9-4 (3D)

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	n .	Mode	of Opera	ition 🏗 📶	Maria C		Kalabet Z. J. J.	an Alba
General (Track I Only)	Specific (Track I & III)	В	М	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other ^{5,}
Ophthalmic	Ophthalmic							
General application	Fetal Abdominal Intra-operative (Specify)? Intra-operative (Neuro) Laparoscopic Pediatric Small Organ	P	P	P		P	P	P ⁵
	(Thyroid, Breast, Testes, etc.) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal	P	P P	P		P	P ·	P ⁵
	Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Conventional)							
,	Musculo-skel. (Superficial) Intra-luminal							
	Other (Specify) (3D/4D)	P	P .	P		P	P	P ⁵
Cardiac	Cardiac Adult Cardiac Pediatric Trans-esoph. (Cardiac) Other (Specify)			•				
Peripheral vascular	Peripheral vascular Other (Specify)				,			

N = new indication; P=previously cleared by FDA 510(k) K082326, E=Added under Appendix E

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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¹ Includes B-Mode and Harmonic (contrast) imaging (HI)

² Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)
Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Freehand tissue elasticity

System Name: ZONARE z.one Ultra Ultrasound Diagnostic System

Device Name: Linear Transducer L10-5

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	on Line and the	Mode	of Opera	tion 🚧 🚣	ant in the		rokanasi d	LANGE
General (Track I Only)	Specific (Track I & III)	В	М	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other ⁵ ,
Ophthalmic	Ophthalmic	N		N		N	N	
	Fetal	P	P	P		P	P	P ⁵
	Abdominal ⁶	P	P	P		P	P	P ⁵
	Intra-operative (Specify) ⁷	P	P	P		P	P	P ⁵
	Intra-operative (Neuro)	P		P		P	P	P ⁵
	Laparoscopic							
	Pediatric	P	P	P		P	P	P ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	P		P	P	P ⁵ P ⁸
	Neonatal Cephalic	P	P	P		P	P	P ⁵
General application	Adult Cephalic	1						
application	Trans-rectal							
	Trans-vaginal							
	Trans-urethral						1	
i	Trans-esoph. (non- Card.)							
	Musculo-skel. (Conventional)	P	P	P		P	P	P ^{5,8}
	Musculo-skel. (Superficial)	P	P	Р		P	P	P ^{5, 8}
	Intra-luminal							
	Other (Specify) ⁸ (3D/4D)							
	Cardiac Adult						T	
,	Cardiac Pediatric		1		}			
Cardiac	Trans-esoph. (Cardiac)							
	Other (Specify)		1				· · · · · · · · · · · · · · · · · · ·	
Peripheral	Peripheral Vascular	P	P	P		P	P	P ⁵ P ⁸
Vascular	Other (Specify) 3D/4D							

N = new indication; P=previously cleared by the FDA 510(k) K022858 & K082326, E=Added under Appendix E

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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510(K) /

¹ Includes B-Mode and Harmonic (contrast) imaging (HI)

² Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)
³ Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

⁴ Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Freehand tissue elasticity

System Name: ZONARE z.one Ultra Ultrasound Diagnostic System

Device Name: Linear Transducer L8-3

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	on Alexander	. Modê	of Opera	tion .	(1000 P. I A	(. 1981 - 1822	S 64.5
General (Track I Only)	Specific (Track I & III)	В	М	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other ^{5,}
Ophthalmic	Ophthalmic	-	-		-	Doppler	Modes	
Ophulannic	Fetal	P ·	P	P		P	P	P ⁵
	Abdominal ⁶	P	P	P		P	P	P ³
	Intra-operative (Specify) ⁷	P	P	P		P	P	P ⁵
	Intra-operative (Neuro)	P		P		P	P	P ⁵
i	Laparoscopic		<u> </u>					
	Pediatric	P	P	P		P	P	P ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	P		P	P	P ⁵
General	Neonatal Cephalic	P	P	P		P	P	P ⁵
application	Adult Cephalic	1					Ì	, , , , , , , , , , , , , , , , , , ,
application	Trans-rectal							
	Trans-vaginal		1				1	
	Trans-urethral		1		-	_		
	Trans-esoph. (non- Card.)							
	Musculo-skel. (Conventional)	P	P	P		P	P	P ^{5, 8}
	Musculo-skel. (Superficial)	P	P	P		P	P	P ^{5, 8}
	Intra-luminal			•				
	Other (Specify) ⁸ 3D/4D	-						
	Cardiac Adult							
	Cardiac Pediatric							
Cardiac	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral	Peripheral Vascular	P	P	P		P	P	P ⁵ P ⁸
Vascular	Other (Specify) 3D/4D							

N = new indication; P=previously cleared by the FDA 510(k) K082326, E=Added under Appendix E Includes B-Mode and Harmonic (contrast) imaging (HI)

Examples may include A-mode, Amplitude Doppler, 3-D imaging, Harmonic imaging, Tissue Motion Doppler, Color velocity imaging

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510(K) KICIOQI	

Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)
Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Freehand tissue elasticity

System Name: ZONARE z.one Ultra Ultrasound Diagnostic System

Device Name: Linear Transducer L12-4v

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Glinical Application	on a second	Mode	of Opera	tion .	HALL OF	**************************************		
General	Specific	В	М	PWD ²	CWD	Color	Combined	Other ^{5,}
(Track I Only)	(Track I & III)		<u>""</u>			Doppler ³	Modes ⁴	8
Ophthalmic	Ophthalmic		· ·	 				
	Fetal		ļ	<u> </u>	·			
	Abdominal		├					
	Intra-operative		'					
:	(Specify) ⁷		<u> </u>					
	Intra-operative	i	1			l .		
	(Neuro)		 	ļ			<u> </u>	
	Laparoscopic			<u> </u>				
	Pediatric	E	E	E	·	E	E	
	Small Organ	l _	l	_		<u> </u>		
	(Thyroid, Breast,	Е	Ė	E		E	E	ļ ·
	Testes, etc.)			ļ				
	Neonatal Cephalic		 				· .	
General	Adult Cephalic		-		<u> </u>	·		
application	Trans-rectal		<u> </u>					·
	Trans-vaginal		ļ					
	Trans-urethral		 					ļ
,	Trans-esoph. (non-			1 '				
	Card.)		 					
	Musculo-skel.	E	E	E		E	Е	l _E
	(Conventional) Musculo-skel.		 		 -	 		
	(Superficial)	E	E	E		E	Ε	l É l
	Intra-luminal		 			<u> </u>		
				 		 -		
	Other (Specify)	_	_				}] :
	(3D/4D)	E	E	E		E	E	Ε .
	(vet use too)						<u>L</u> .	[
	Cardiac Adult							
	Cardiac Pediatric		ļ					
Cardiac	Trans-esoph.							
	(Cardiac)							
	Other (Specify)		ļ			<u> </u>		
Peripheral	Peripheral vascular	Е	E	E		E	E	Е
vascular	Other (Specify)							

N = new indication; P=previously cleared by FDA, E=Added under appendix E, lncludes B-Mode and Harmonic (contrast) imaging (HI)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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510(K) KIN109

² Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)
Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Freehand tissue elasticity

System Name: ZONARE z.one Ultra Ultrasound Diagnostic System

Device Name: Linear Transducer L14-5sp

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	on the second	Mode	of Opera	tion 🔭 🚜	25 h e y		V1-3	
General (Track I Only)	Specific (Track I & III)	В	М	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other ³ ,
Ophthalmic	Ophthalmic							
	Fetal	P	P	P		P	P	P ⁵ ·
	Abdominal ⁶	P	P	P		P	P	P ⁵
	Intra-operative (Specify) ⁷	P	P	P		P	Р	P ⁵
	Intra-operative (Neuro)	P		P		P	P	P ⁵
	Laparoscopic				ļ			ļ
	Pediatric	P	P	P		P	P	P ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	P		P	P	P ⁵
	Neonatal Cephalic	P	P	P		P	P	P ⁵
General	Adult Cephalic			1		ĺ		
application	Trans-rectal	1		i				1
	Trans-vaginal	1 .				T		
	Trans-urethral					l .		
	Trans-esoph. (non- Card.)							
	Musculo-skel. (Conventional)	P	P	Ρ.		P	P	P ^{5, 8}
	Musculo-skel. (Superficial)	P	P	P		P	P	P ^{5, 8}
	Intra-luminal		J	Ť,				
	Other (Specify) ⁸ 3D/4D							
	Cardiac Adult							<u> </u>
	Cardiac Pediatric							
Cardiac	Trans-esoph. (Cardiac)						t .	<u> </u>
	Other (Specify)							ļ,
Peripheral	Peripheral Vascular	P	P	P		P	P	P ⁵ P ⁸
Vascular	Other (Specify) 3D/4D							

N = new indication; P-previously cleared by the FDA 510(k) K082326, E=Added under Appendix E

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD) Division Sign-Off Office of In Vitro Diagnostic Devices Evaluation and Safety
510(K) <u>[[] [] [] [] [] [] [] [] [] </u>

¹ Includes B-Mode and Harmonic (contrast) imaging (HI)

² Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

³ Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

⁴ Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Freehand tissue elasticity

Examples may include A-mode, Amplitude Doppler, 3-D imaging, Harmonic imaging, Tissue Motion Doppler, Color velocity imaging

510(K) Number (if known): System Name ZONARE z.one Ultra Ultrasound Diagnostic System

Device Name: Linear Transducer L14-5w

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	on.	Mode	of Opera	tion.		PENERAL	FW KV	N STEW
General (Track I Only)	Specific (Track I & III)	В	М	PWD ²	CWD	Color Doppler ³ ,	Combined Modes ⁴	Other ^{5,}
Ophthalmic	Ophthalmic			٠.				
	Fetal	P	P	P		P	P	P ⁵
	Abdominal ⁶	P	P	P		P	P	P ⁵
	Intra-operative (Specify) ⁷	P	P	P		P.	P	P ⁵
	Intra-operative (Neuro)	P		P		P	P	P ⁵
	Laparoscopic					<u> </u>		
	Pediatric	P	P	P		P	P	P ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	. P		P	P	P ⁵
General	Neonatal Cephalic	P	P	P	-	P	P	P ⁵
application	Adult Cephalic							
application	Trans-rectal							
	Trans-vaginal							
	Trans-urethral		<u> </u>		· · · · · ·			
	Trans-esoph. (non- Card.)							
	Musculo-skel. (Conventional)	P	P	P		P	P	P ^{5, 8}
	Musculo-skel. (Superficial)	P	P	P		P	P	P ^{5, 8}
	Intra-luminal							<u> </u>
	Other (Specify) ⁸ 3D/4D				!			
	Cardiac Adult							
	Cardiac Pediatric					<u> </u>		
Cardiac	Trans-esoph. (Cardiac)					,		
	Other (Specify)					l		
Peripheral	Peripheral Vascular	P	P	P		P	P	P ⁵ P ⁸
Vascular	Other (Specify) 3D/4D	·						

N = new indication; P=previously cleared by the FDA 510(k) K082326, E=Added under Appendix E

Examples may include A-mode, Amplitude Doppler, 3-D imaging, Harmonic imaging, Tissue Motion Doppler, Color velocity imaging

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Office of In Vitro Diagnostic Devices	
Evaluation and Safety	
510(K) K101091	

Includes B-Mode and Harmonic (contrast) imaging (HI)

Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Freehand tissue elasticity

510(K) Number (if known):	
System Name: ZONARE z.one Ultra	Ultrasound Diagnostic System

Device Name: Tran-Esophageal Transducer: P8-3T

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	on we want	Mode	of Opera	tion 💮 📜			2.53400.0	. V . 1
General (Track I Only)	Specific (Track I & III)	В	М	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other ^{5,}
Ophthalmic	Ophthalmic		1					
•	Fetal				,	,		
	Abdominal					<u> </u>		
	Intra-operative (Specify) ⁷	,						<u></u>
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	<u> </u>		<u> </u>				
	Small Organ (Thyroid, Breast, Testes, etc.)	,						
•	Neonatal Cephalic		 	 				
General	Adult Cephalic		 	 	 			
applications	Trans-rectal		 	1		 	-	
	Trans-vaginal		1		ľ			
	Trans-urethral	1		<u> </u>	<u> </u>	1		
	Trans-esoph. (non- Card.)	P	P	P	P	P	P	P ⁵
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal			l				1
	Other (Specify) (3D/4D)							·
	Cardiac Adult							<u> </u>
	Cardiac Pediatric				<u> </u>		·	
Cardiac	Trans-esoph. (Cardiac)	P	P	P	P	P	P	P ⁵
	Other (Specify)						ļ	
Peripheral	Peripheral Vessel				<u> </u>		ļ	<u> </u>
Vessel	Other (Specify)		<u> </u>			1		

N = new indication; P=previously cleared by FDA 510(k) K082326, E=Appendix E

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510(K) <u>K10.1()9</u>

¹ Includes B-Mode and Harmonic (contrast) imaging (HI)

² Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

³ Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

⁴ Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)
⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Freehand tissue elasticity

System Name: ZONARE z.one Ultra Ultrasound Diagnostic System

Device Name: St. Jude EP ViewFlex PLUS ICE Catheter model # VF-PM Part #09-2005 Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	n S. J. S.	Mode o	f Opera	tion	Maria San	16.00		W/W
General (Track I Only)	Specific (Track I & III)	В	М	PWD ²	CWD	Color Doppler	Combined Modes ⁴	Other ^{5,}
Ophthalmic	Ophthalmic							
	Fetal						l	
	Abdominal							
	Intra-operative (Specify) ⁷					,		
	Intra-operative (Neuro)				<u> </u>		1	
	Laparoscopic					Ţ.		
	Pediatric			l		<u> </u>		
	Small Organ (Thyroid, Breast, Testes, etc.)							
,	Neonatal Cephalic			 	1		-	<u> </u>
General	Adult Cephalic							1
application	Trans-rectal			<u> </u>	-			
аррисацон	Trans-vaginal							
	Trans-urethral					-	<u> </u>	
	Trans-esoph. (non- Card.)							
	Musculo-skel. (Conventional)						ļ	
	Musculo-skel. (Superficial)							
	Intra-luminal	· · ·		1	 		1	
Other	Other (Specify) (3D/4D)							
Cardiac	Cardiac Adult		Ì					
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intra-Cardiac)	P	P	P		P		
Peripheral	Peripheral vascular		·					
vascular	Other (Specify)		1					

N = new indication; P=previously cleared by FDA 510(k) K031066 & K073709, E=Added under Appendix E

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Evaluation and Safety

510(K) K101091

¹ Includes B-Mode and Harmonic (contrast) imaging (HI)

² Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

³ Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

⁴ Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Freehand tissue elasticity

510(K) Number (if known):	·
System Name: ZONARE 7 one I	Iltra Illtrasound Diagnostic System

Device Name: A2CW (Common name Pencil Probe)

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Glinical Application	on the second	Mode	of Opera	tion 👫 .	No.			医海色学
General (Track I Only)	Specific (Track I & III)	В	М	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other ^{5,}
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal							
	Intra-operative (Specify) ⁷							
	Intra-operative							
	(Neuro)		ļ					
	Laparoscopic		ļ					
	Pediatric		 		P ··			
	Small Organ		1			ŧ		
	(Thyroid, Breast,		i					
	Testes, etc.)		ļ	<u> </u>	ļ	<u> </u>		
	Neonatal Cephalic	ļ	ļ		 	 		
General	Adult Cephalic	 	 	 	<u> </u>			
application	Trans-rectal		<u> </u>	 	 			
	Trans-vaginal		· · · · · · · · · · · · · · · · · · ·	 				
	Trans-urethral		 	ļ			<u>'</u>	
	Trans-esoph. (non- Card.)							
	Musculo-skel.	ł	}					
	(Conventional)		.]	ļ	ļ			
	Musculo-skel.	l .						
	(Superficial)		-	<u> </u>				<u> </u>
	Intra-luminal		 	 	 	ļ		
,	Other (Specify) (3D/4D)							
	Cardiac Adult		1		P			1
	Cardiac Pediatric				P			I
Cardiac	Trans-esoph.							
	(Cardiac)				,	<u> </u>	<u> </u>	<u> </u>
	Other (Specify)							
Peripheral	Peripheral vascular							
vascular	Other (Specify)							

N = new indication; P=previously cleared by FDA 510(k) K082326, E=Appendix E

1 Includes B-Mode and Harmonic (contrast) imaging (HI)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Office of In Vitro Diagnostic Devices **Evaluation and Safety**

510(K)

Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Freehand tissue elasticity

510(K) Number (if known): System Name: ZONARE z.one Ultra Ultrasound Diagnostic System

Device Name: A5CW (Common name Pencil Probe)

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	onte	Mode	of Onera	tion a way	Envisore Su		Contract and	Paris and District and the second
General (Track I Only)	Specific (Track I & III)	В	М	PWD ²	CWD	Color Doppler ³	Combined	Other ^{5,}
Ophthalmic	Ophthalmic	 		 	 	Doppler	Modes ⁴	<u> </u>
General application	Fetal Abdominal Intra-operative (Specify) ⁷ Intra-operative (Neuro) Laparoscopic Pediatric Small Organ (Thyroid, Breast, Testes, etc.) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-urethral Trans-urethral Conventional) Musculo-skel. (Conventional) Musculo-skel. (Superficial) Intra-luminal Other (Specify) (3D/4D)				P			
Cardiac	Cardiac Adult Cardiac Pediatric Trans-esoph. (Cardiac) Other (Specify)							
Peripheral	Peripheral vascular	 			_			
vascular	Other (Specify)				P			
M = = out in direction	(5,000)							

N = new indication; P=previously cleared by FDA 510(k) K082326, E=Appendix E Includes B-Mode and Harmonic (contrast) imaging (HI)

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510(K) K101091

² Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

³ Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Freehand tissue elasticity